Module 8:
Risk Assessment

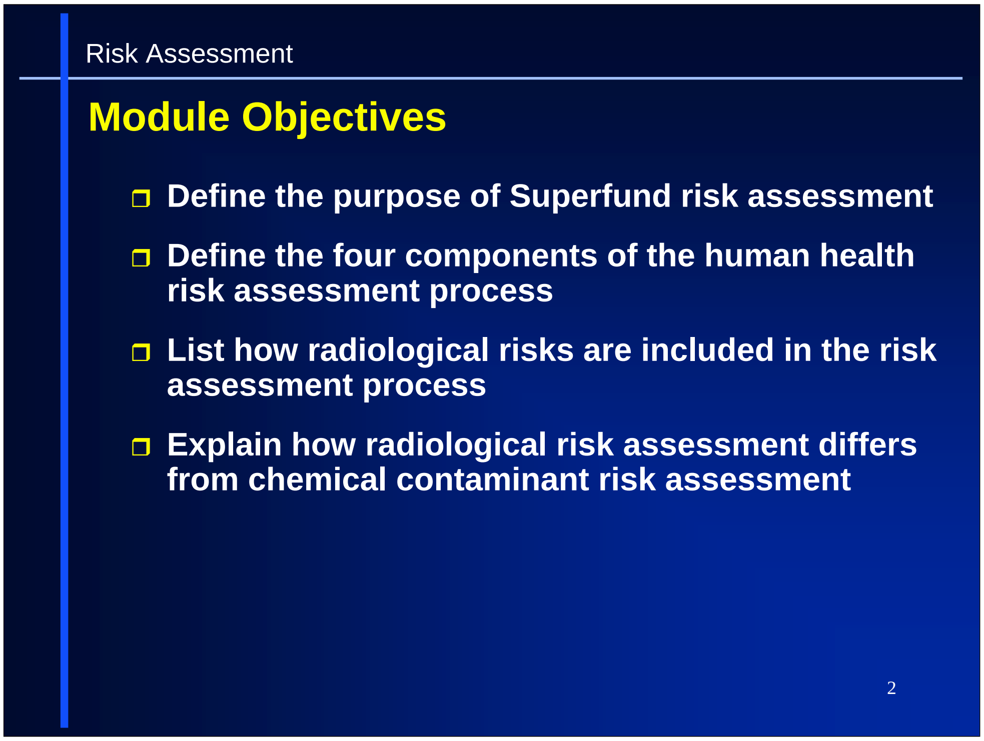
- This section discusses the main steps in the human health risk assessment process:

  - contaminant identification
  - exposure assessment
  - toxicity assessment
  - risk characterization
  - risk communication

- An additional section will specifically introduce radiological risk assessment.

- Key references:

  - *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*, Interim Final, December 1989, EPA/540/1-89/002.
  - *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part B)*, Development of Risk-Based Preliminary Remediation Goals, 1991, EPA/540/1-89/002.
  - *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part C)*, Risk Evaluation of Remedial Alternatives, 1991, EPA/540/1-89/002.


Risk Assessment
Module Objectives
Define the purpose of Superfund risk assessment
Define the four components of the human health risk assessment process
List how radiological risks are included in the risk assessment process
Explain how radiological risk assessment differs from chemical contaminant risk assessment
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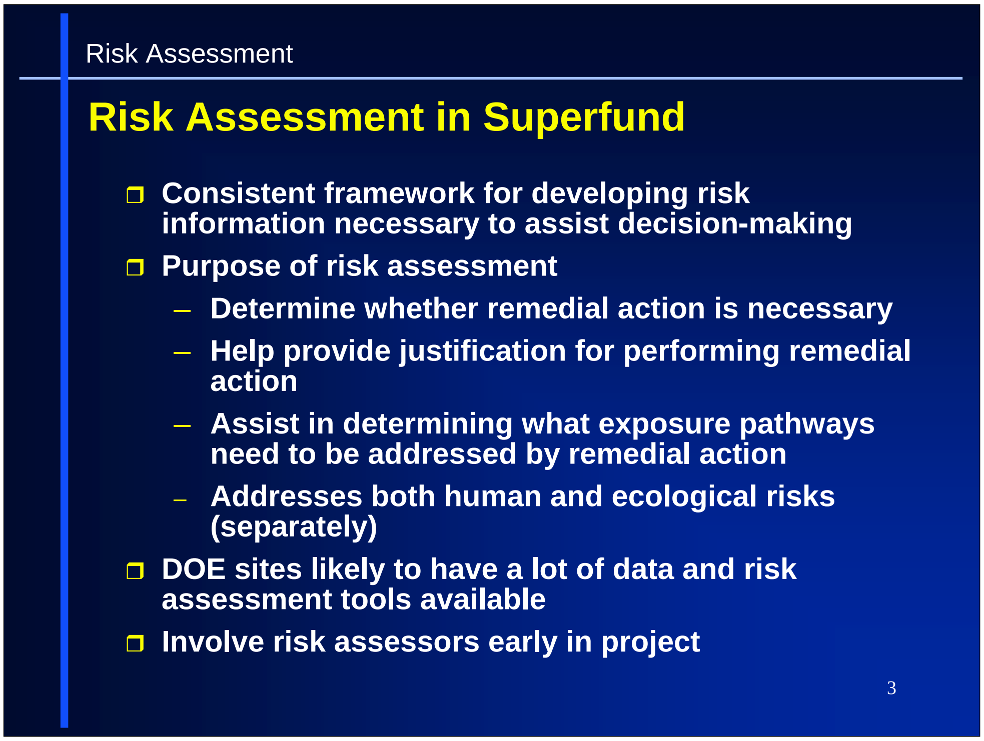


- Why do risk assessment?

  - It provides the decisionmaker with information to determine whether there is unacceptable risk and imminent substantial endangerment (i.e., a basis for taking remedial action in Superfund).

  - The Hazard Ranking System (HRS) listing is not always an accurate representation of risk because of limited information.

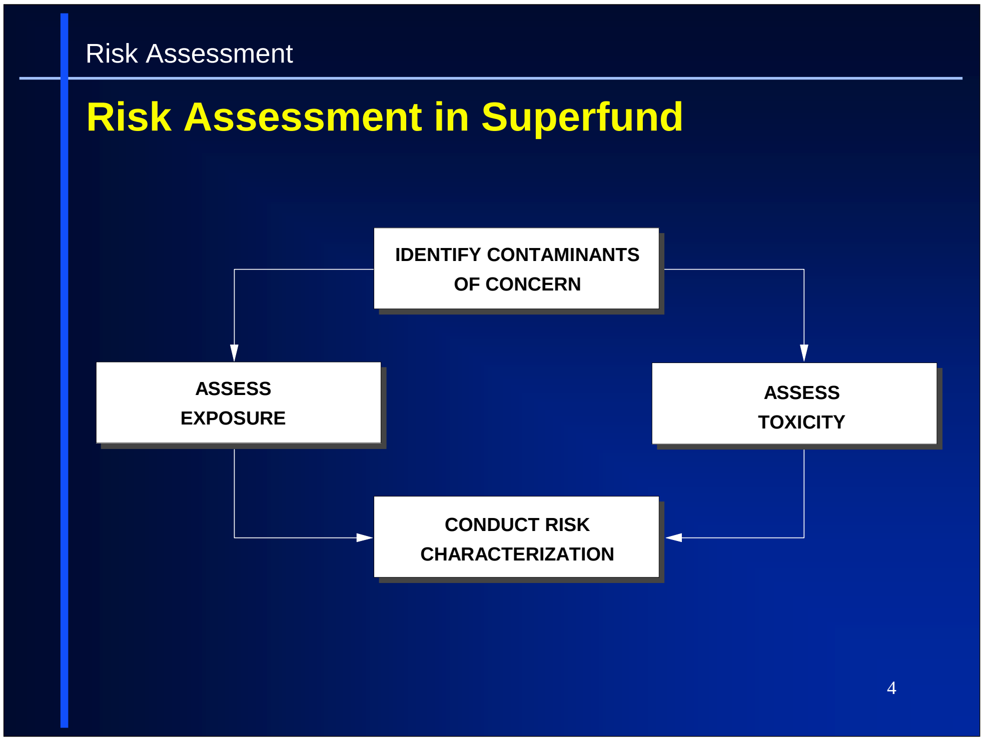
  - If there is an unacceptable risk, it provides some of the documentation necessary to justify action.

  - It helps to indicate what exposure pathways at site need to be addressed by the action.

- Risk assessment addresses both human health & the environment. This section focuses mainly on human health.

- Risk assessment is generally performed during the RI. In the FS, preliminary remediation goals are refined based on risk assessment and ARARs.

- Risk assessments are generally quantitative. They may be qualitative or less detailed to support early or interim actions.

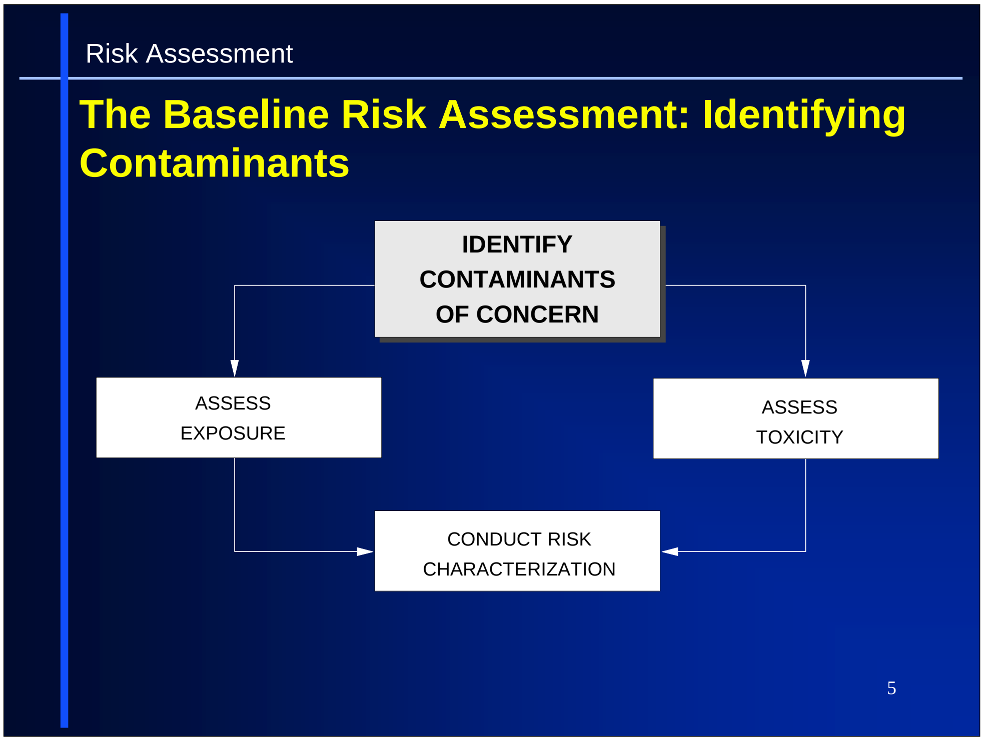


- The human health risk assessment process has four major components -- based on the four components recommended by National Academy of Science in the early 1980s.

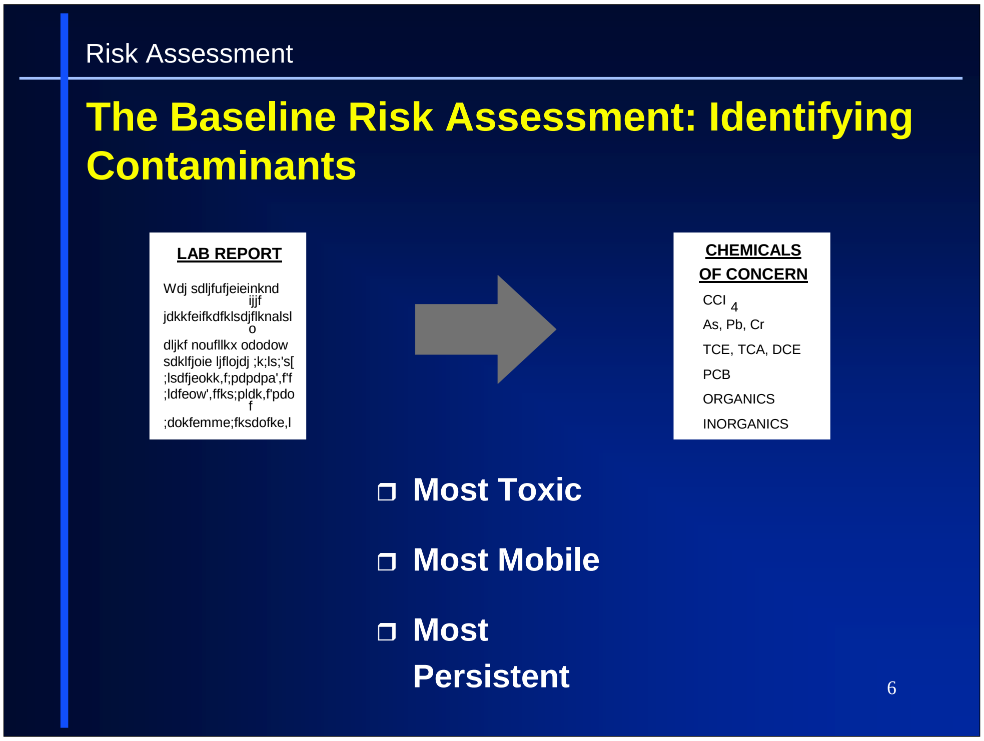
  - Identify chemicals that will be the focus of the assessment
  - Determine how people and ecological receptors can be exposed to those chemicals
  - Assess the inherent toxicity of the contaminants
  - Evaluate the effect of those chemicals at the levels people will be exposed in order to estimate the risk to humans

- The scope and extent of risk assessment will vary based on site-specific conditions.

- Identifying data requirements is critical to a successful risk assessment.



- The first step in the risk assessment process is to determine what chemicals will be the focus of the assessment. This step is also known as Data Collection and Evaluation.
- <u>Initial</u> input will be based on the HRS package and historical records that identify certain chemicals thought to be present at the site and potentially of concern.



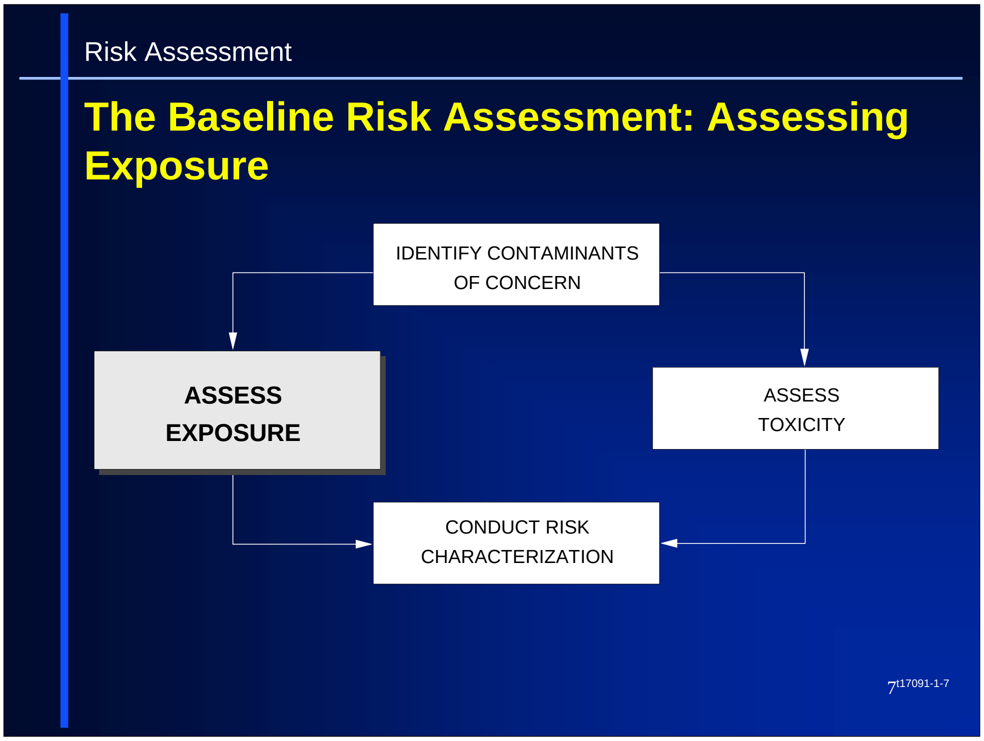
- This is the data evaluation step.

- From laboratory report, identify those chemicals that are likely to be associated with significant risk based on concentration/toxicity, mobility, persistency.

- It will not be necessary to look at every chemical on site because some will be:

  - below level of concern (for example, when compared to MCLs)
  - below level of toxicity concern (based on a standard exposure assumption, there is an acceptable risk)
  - within or below background

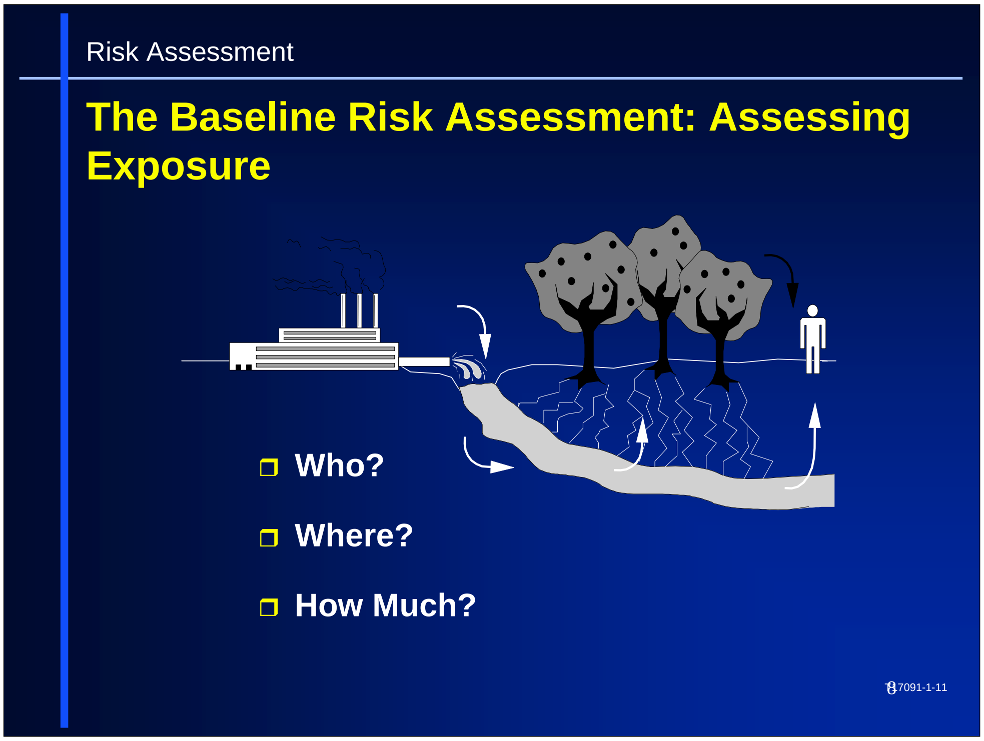
- See the *Risk Assessment Guidance for Superfund* for specific guidelines on eliminating potential chemicals of concern from a study.



- Now that you know what chemicals you are dealing with, you can begin to assess exposure.

- In a human health evaluation, focus on how people may come in contact with contaminants, what the levels of exposure will be, and what intake pathways are likely.

- Assimilate investigation results from the RI (need consistency in fate and transport and potential exposures).



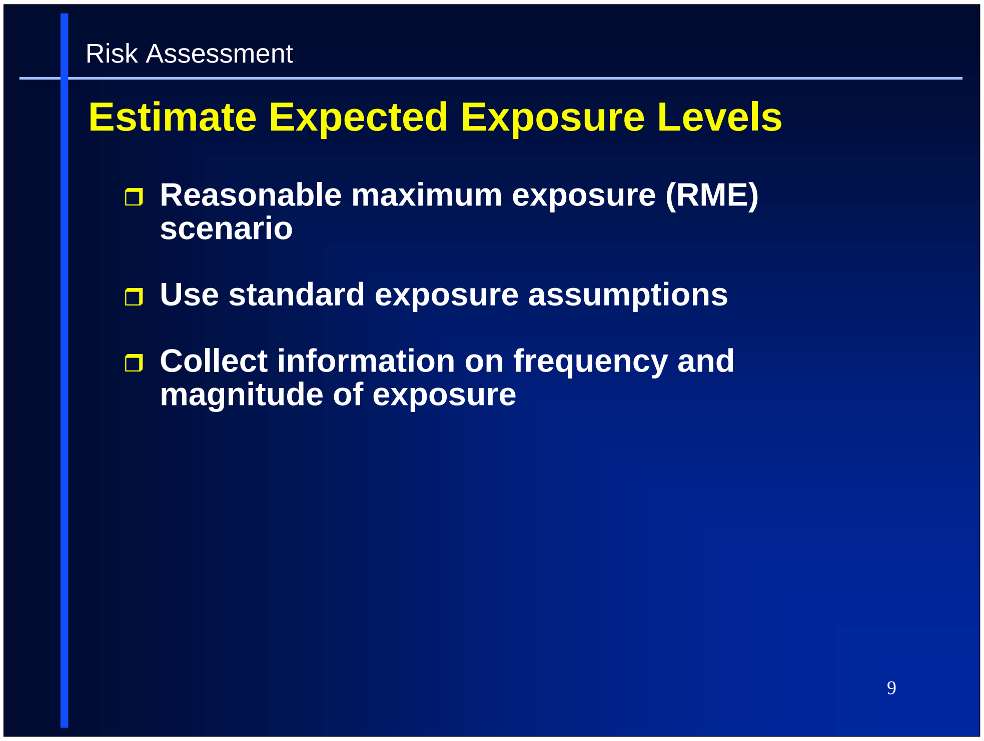
- *Who?* Identify actual and potentially exposed populations (e.g., on- or off-site populations, workers, future residents).

- *Where?* Identify a variety of pathways through which people could be exposed to site-related contaminants:

  - Direct contact with contaminated surface water or soil
  - Ingestion and domestic use of contaminated groundwater
  - Inhalation of VOCs or wind-blown dust composed of metals or with organics sorbed to the dust particles

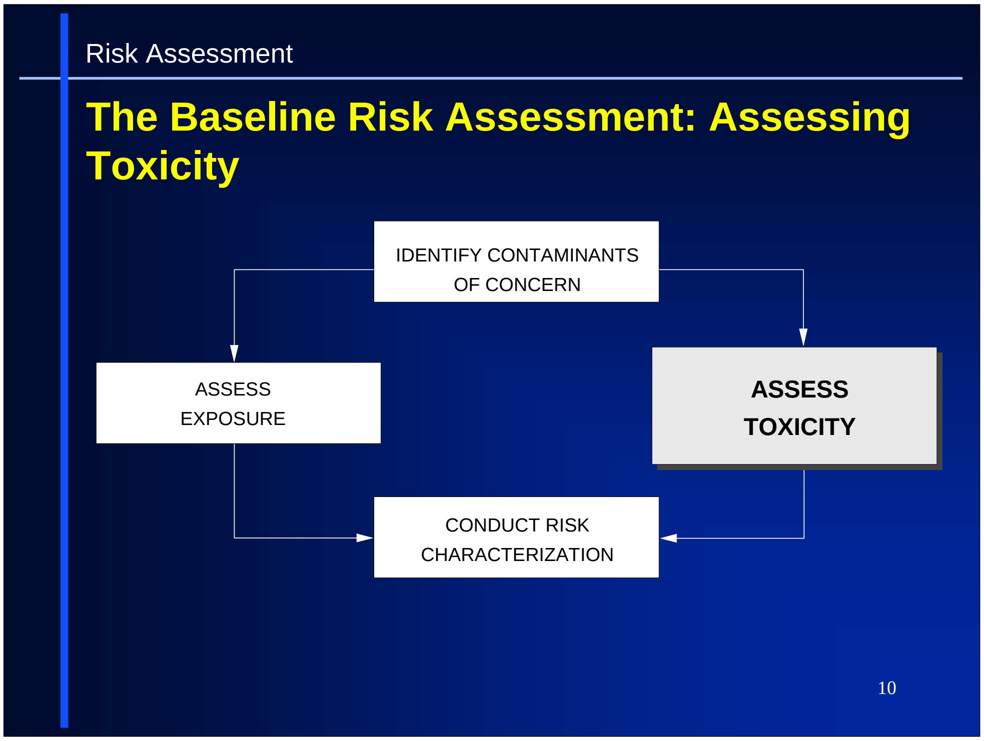
- *How much?* Estimate intake. You may consider:

  - Exposure point concentrations
  - Contact rate
  - Exposure frequency/duration
  - Body weight
  - Exposure averaging time



- Reasonable maximum exposure (RME) is the highest exposure that is reasonably expected to occur at a site considering land use, intake variables, and pathway combinations. The intent is to estimate a conservative exposure case that is still within the range of possible exposures.

- No longer evaluate average and worst case scenarios.



- Generally, toxicity assessment is already done. Use EPA-developed toxicity data from IRIS and HEAST.

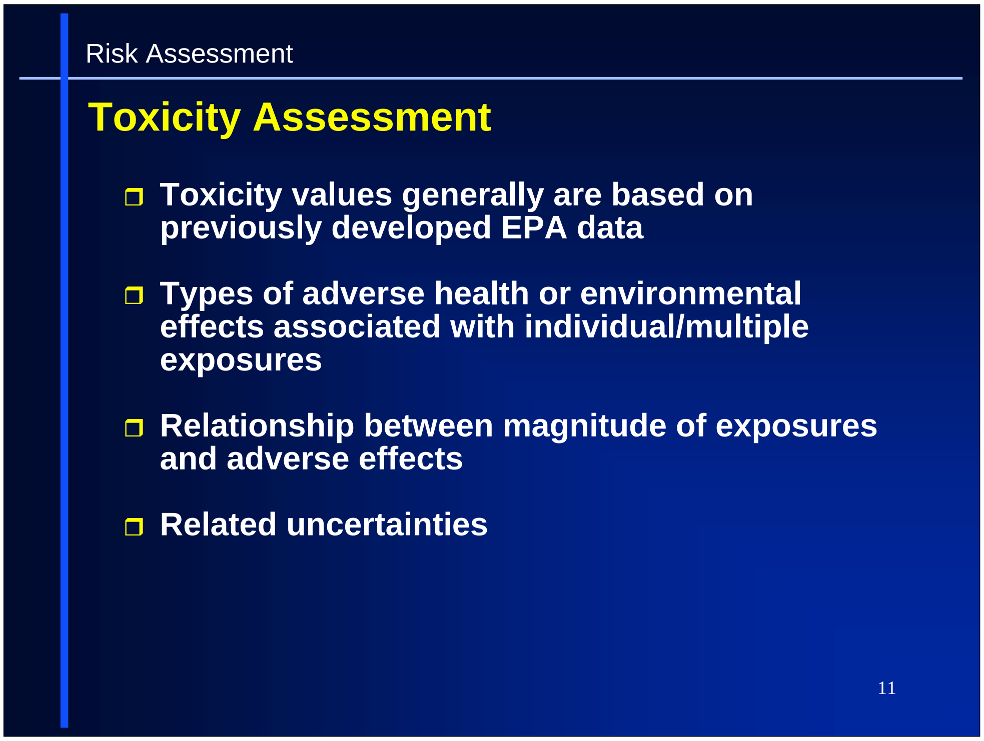
- IRIS (Integrated Risk Information System) is EPA's primary reference source, reflecting Agency-wide consensus. It provides verified RfDs and slope factors.

- HEAST (Health Effects Assessment Summary Tables) is produced for the Superfund program to complement IRIS and provide for accurate, timely assessments. It provides interim as well as verified RfDs and slope factors.

- Toxicity assessment generally is accomplished in two steps: <u>hazard identification</u> and <u>dose-response assessment</u>.

- <u>Hazard identification</u> is the process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health effect.

- <u>Dose-response evaluation</u> is the process of quantitatively evaluating the toxicity information and characterizing the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population.



- The toxicity assessment considers (1) the types of adverse health effects associated with chemical exposures; (2) the relationship between magnitude of exposure and adverse effects; and (3) related uncertainties such as the weight of evidence of a particular chemical's carcinogenicity in humans.

- There are two major modes of toxicity:
  - <u>Carcinogenic</u> -- These have no threshold; any exposure is associated with some risk
  - <u>Systemic noncarcinogenic</u> (classic poison)

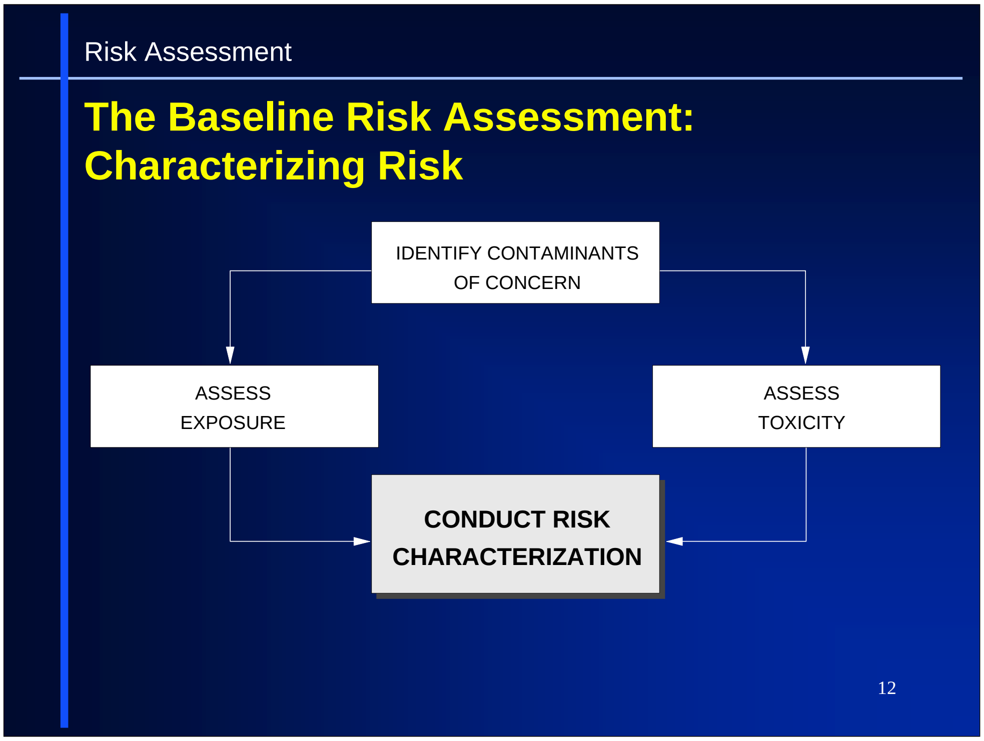
- Toxicologists assess the cancer-causing potential of a substance by studying the effects of different doses, often on laboratory animals. Doses that result in a sufficient number of tumors in a small population of animals to be statistically significant are often much higher than would occur at the concentration of a substance at a Superfund site or somewhere else in the environment. Thus, models are used to extrapolate effects from high (laboratory) dose to low (environmental) dose.

- Our current understanding of carcinogenicity suggests that even at very low doses, there is some probability of response.

- A weight-of-evidence determination is part of the toxicity data most commonly used to evaluate potential human carcinogenic risks.

- In assigning a weight-of-evidence classification, available data are evaluated to determine the likelihood that an agent is a human carcinogen. The agent is then given one of the weight-of-evidence classifications shown above.

- Different doses of noncarcinogens result in different responses. In this case, there is a low dose for which there is no observed adverse effect (NOAEL) (i.e., there is a threshold). To protect for uncertainties (e.g., applying the results of animal studies to effects in humans), EPA divides the NOAEL dose by one or more uncertainty factors (UF) to determine a Reference Dose (RfD) that is probably "safe."



- In the final step of risk assessment, we combine exposure and toxicity assessment to characterize risks.

Risk Assessment

Risk Characterization

- Should summarize:
  - Contaminants of concern
  - Exposure evaluation
  - Weight of evidence (especially for toxicity information)
  - Risks associated with each potential route of exposure and contaminant of concern at the site
- Should discuss any major uncertainties in assumptions or expectations

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- It may be appropriate to combine risk from various media (e.g., risk from drinking groundwater + risk from direct contact with soil).

- There always will be uncertainties associated with model applicability and assumptions, toxicity values, etc. Risk characterization considers these major uncertainties.

Risk Assessment

Risk Communication

- Explaining magnitudes - drop in swimming pool = mg/l
- Comparing risks
- Explaining risk versus hazard
- Describing risk perception

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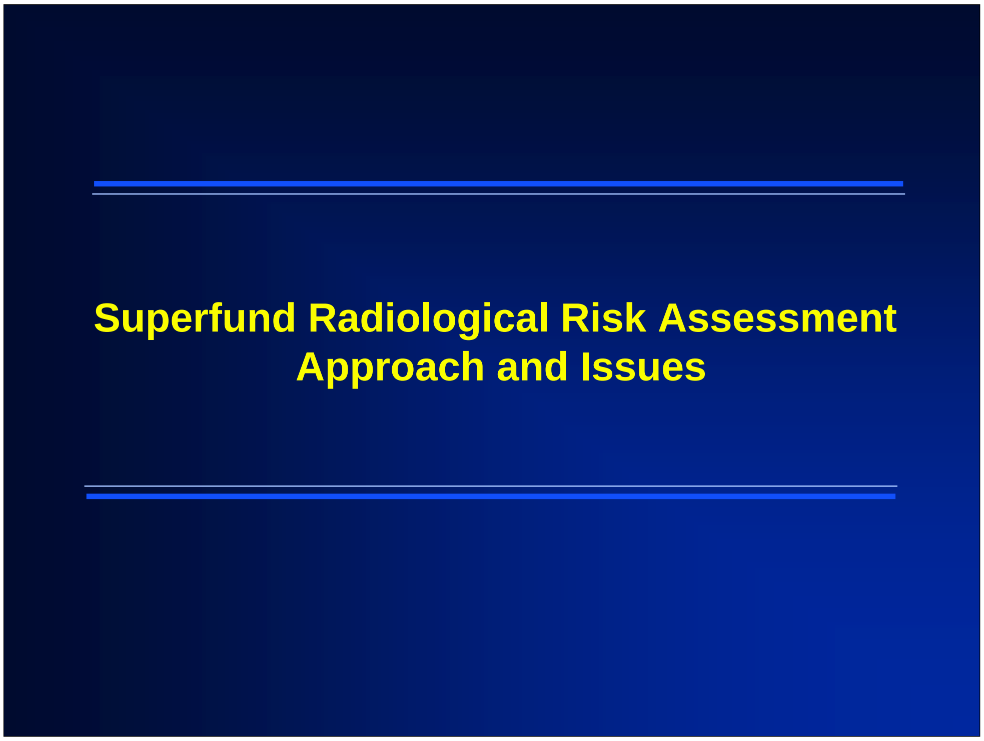
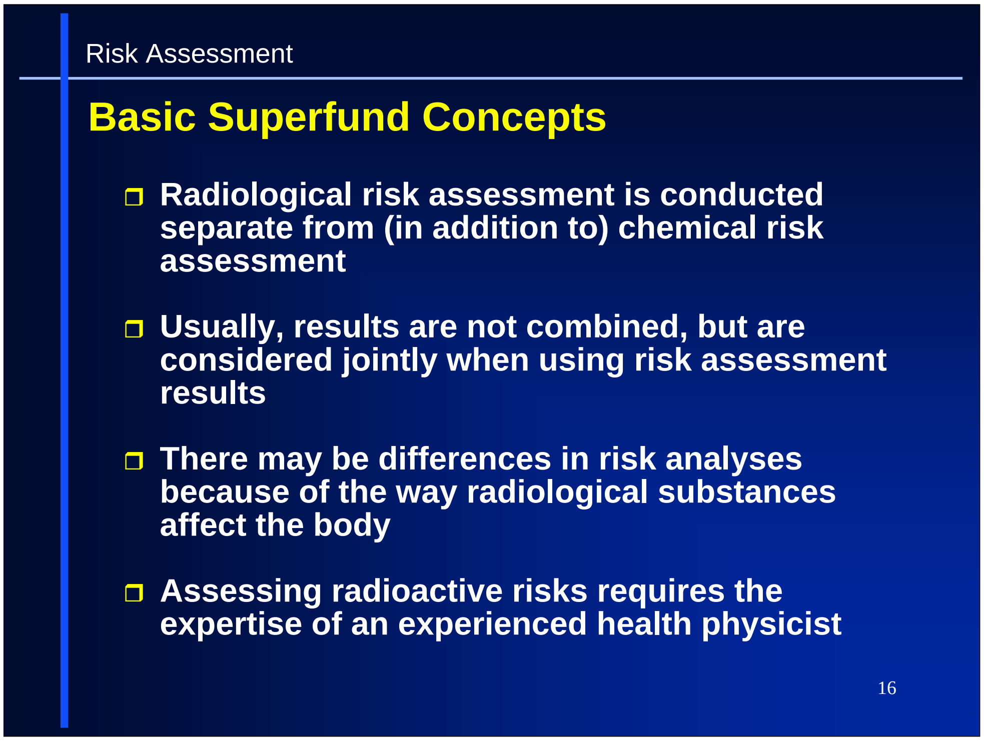


- This section discusses basic radiation concepts and how they apply to risk assessment.
- The key reference is Chapter 10 of the *Risk Assessment Guidance for Superfund*, Volume I.

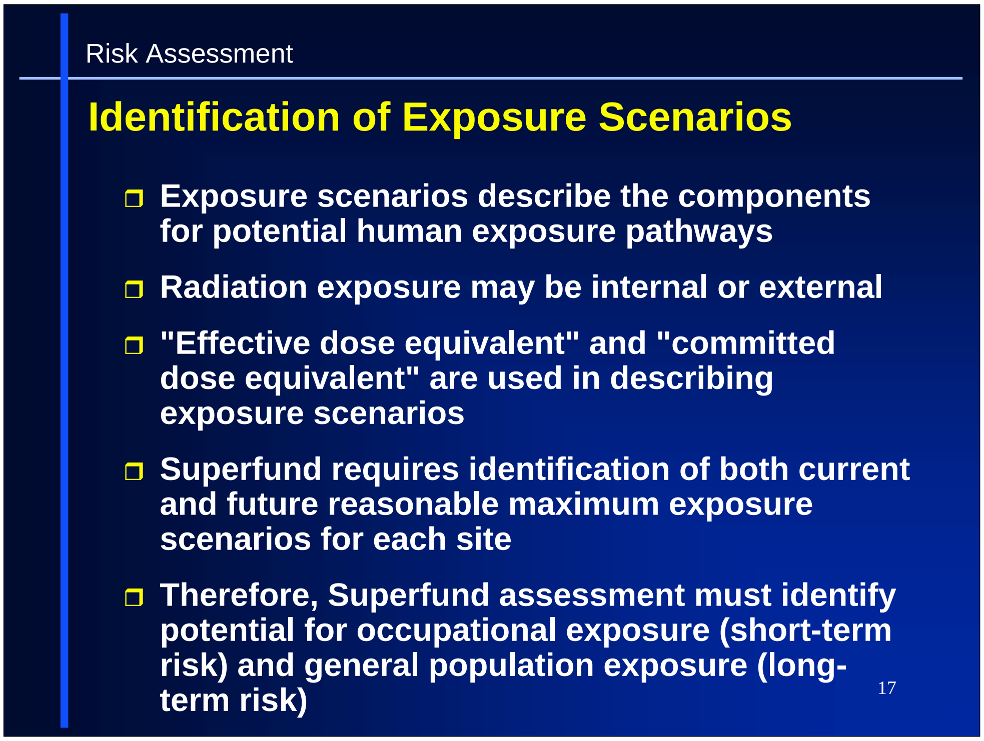


- Radiological and chemical analyses are two parts of a human health risk assessment. They require different skills, expertise, and approaches. However, results are considered together.

- The DOE manager should consult an experienced health physicist throughout the entire RI/FS process, including risk assessment.

- The role of the health physicist may include risk-related assessments in addition to other duties:

  - Defining the physical characteristics of the site, potentially impacted populations, and pathways of concern
  - Analyzing fate and transport models used
  - In general, aiding the DOE manager in estimation of risk
  - Performing radiation sampling or measurements
  - Coordinating health and safety planning of remedial actions



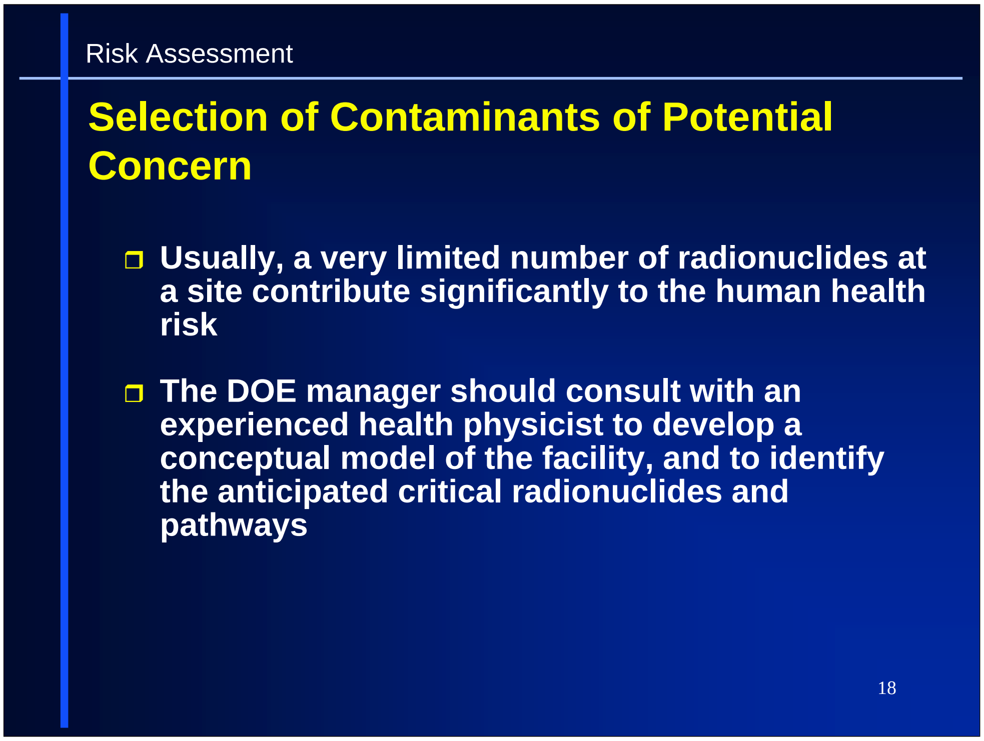
- Internal exposure refers to an exposure that occurs when human tissues are subjected to radiation from radionuclides that have entered the body via inhalation, ingestion, injection, or other routes.

- External exposure refers to the irradiation of human tissues by radiation emitted by radionuclides located outside the body either dispersed in the air or water, on skin surfaces, or deposited on ground surfaces.

- The dose delivered to tissues from external exposure occurs only while the radiation field is present. However, the dose delivered to body tissues due to radiation from systematically incorporated radionuclides may continue long after intake of the nuclide has stopped.

- A current reasonable maximum exposure scenario will identify the radiation exposure to the residents nearest the site, nearest population, and/or sensitive individuals. A future reasonable maximum exposure scenario will identify the radiation exposure to resident/population at point of highest contamination concentration.

- Like chemical risk, we use the concept of "reasonable maximum" scenario because, in many exposure scenarios, adjusting all parameters to their limiting values would maximize exposure but may not have a realistic chance of happening in the real world. In reasonable maximum scenarios, the exposures may be high, but the combination of exposure parameters for an individual are those that are more likely to occur in the population.



- Long-lived radionuclides are often of the most significant concern for risk assessments because of their long-term threat.

Risk Assessment

Exposure Assessment

- Virtually identical for radioactively contaminated sites and for chemically contaminated sites
- Sites with radionuclide contamination should conduct a survey to determine external radiation levels
- For chemical exposure, units are mg/kg-day. Radionuclide exposure is typically expressed in units of activity (i.e., Curie) rather than mass
- Like chemicals, a radionuclide's transfer rate into the environment must be examined
- Biological and chemical transformation can never alter the radioactivity of a radionuclide, whereas chemical contamination may be dramatically affected by these processes

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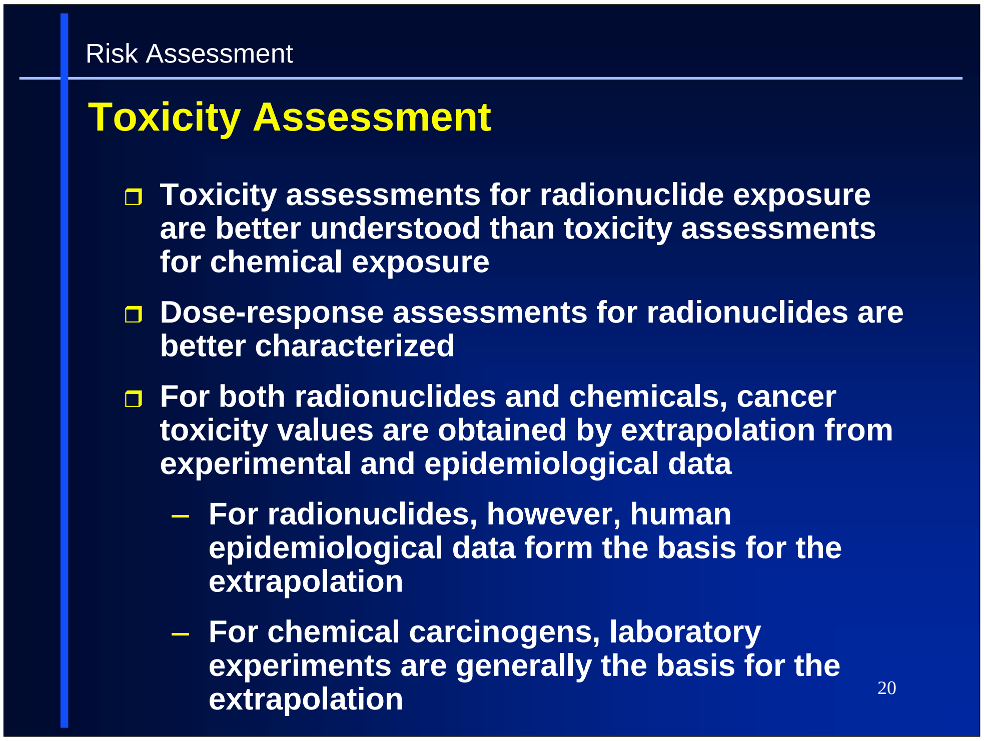
- A Curie is defined as the quantity of a given radionuclide in which 3.7×10^{10} atoms undergo nuclear transformations each second.

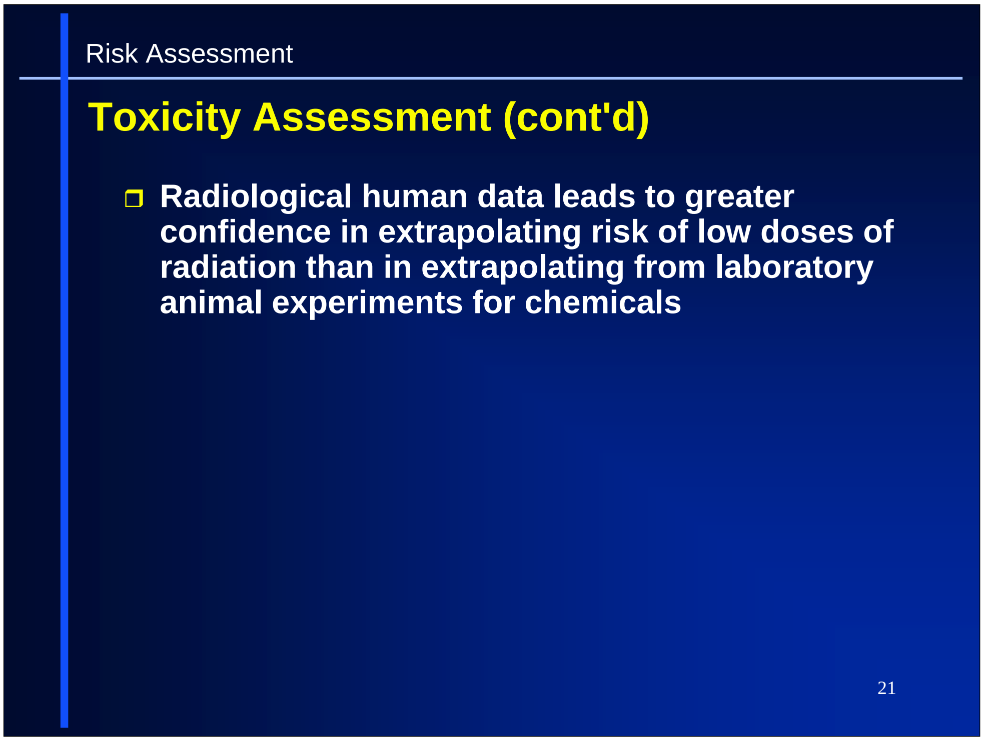
- A survey for external radiation is important because, unlike chemicals, radionuclides can do harm without being taken into or brought into contact with the body.

- Radioactive decay products can significantly contribute to the radiation exposure and must be considered in the assessment.

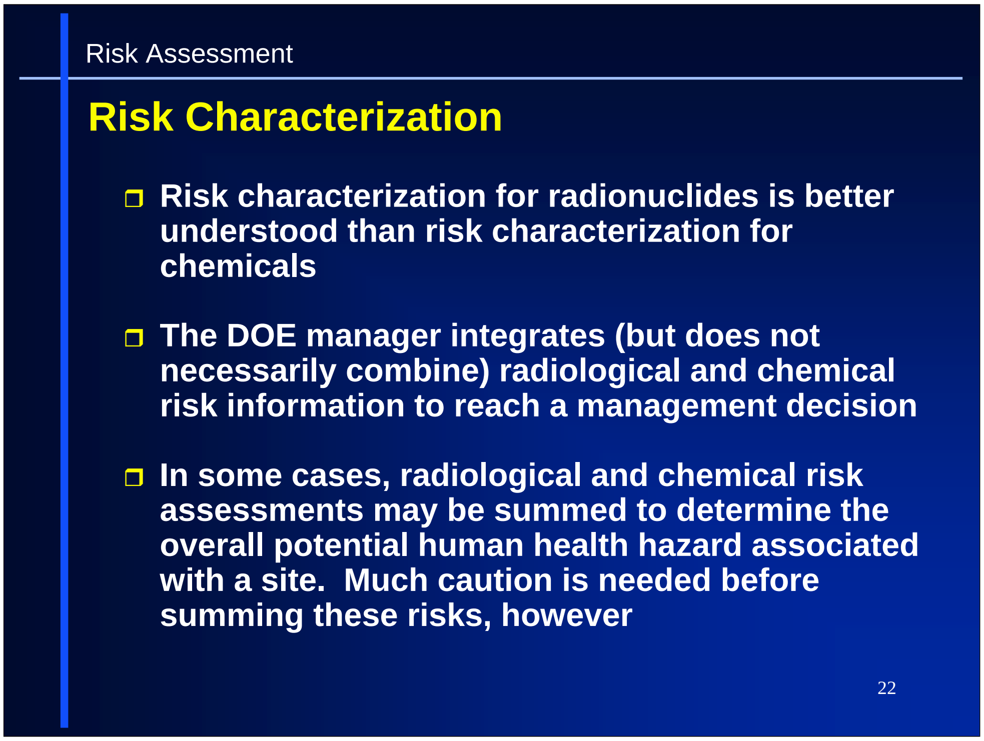
- As with chemicals, environmentally dispersed radionuclides are subject to the same chemical processes that may accelerate or retard their transfer rates and may increase or decrease their bioaccumulation potentials. These transformation processes must be taken into consideration during the exposure assessment.



- Unlike the "threshold" responses of many chemicals, any dose of radiation is assumed to have the potential to produce an adverse effect. Accordingly, exposure to any radioactive substance is hazardous.



- The relationship between dose and effect is relatively well-characterized (at high doses) for most types of radiation because of human epidemiological data. In general, more human radiological data is available for radiological toxicity assessments than human chemical data is available for chemical toxicity assessments. For example, much human radiological data is available from World War II and Chernobyl studies.



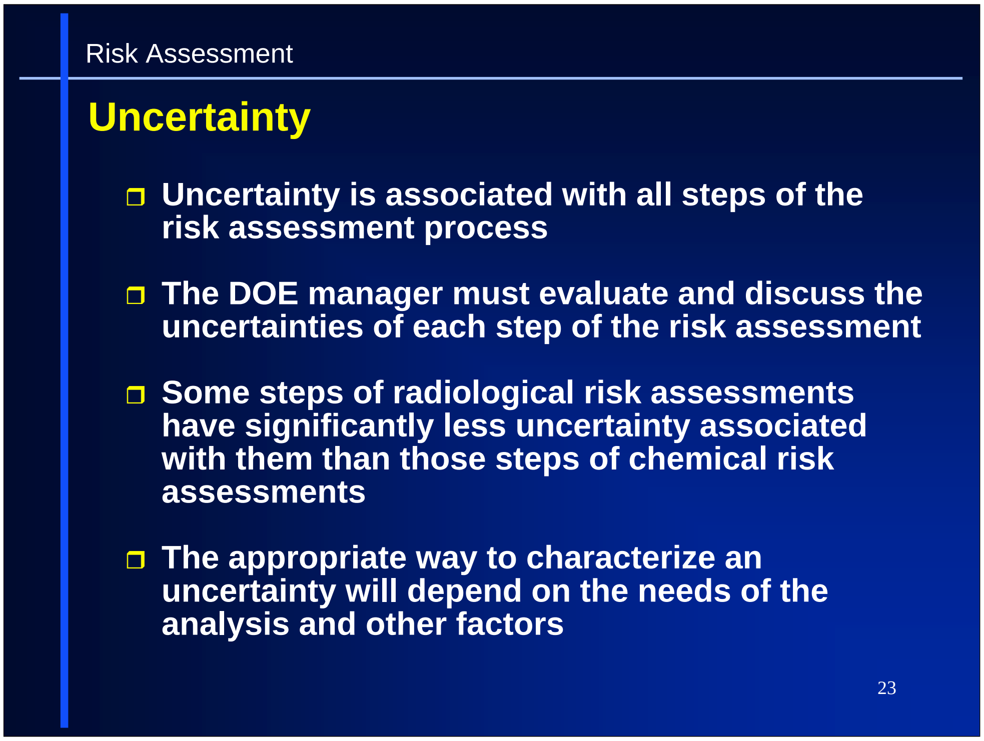
- Risk characterization is better understood for radionuclides because many of the confounding factors of a chemical risk characterization do not need to be considered: only radiation carcinogenesis needs to be considered.

- Before summing chemical and radiological risks, the manager should:

  - Evaluate whether it is reasonable to assume that the same individual can receive the maximum radiological and chemical dose. It is possible for this to occur in some cases because many of the environmental transport processes and routes of exposure are the same for radionuclides and chemicals

  - Evaluate the different assumptions that may have been used in environmental fate and transport models

  - Consult an experienced health physicist



- Less uncertainty is involved in the step of defining levels of radioactive contamination because radiation detection and analytical techniques used are more precise and sensitive than those used in chemical detection.

- At a chemically-contaminated site, there can be many potential and difficult-to-point offsite sources for the contamination found onsite, confounding the interpretation of field measurements. With a radioactively-contaminated site, however, this not usually a problem because sources of radiation are easier to isolate and identify.

- Selecting the appropriate way to characterize an uncertainty depends upon:

  - The type of decision the analysis supports
  - Confidence level required
  - Model type
  - Quantity type
  - Extent and quality of information
  - The method used to estimate uncertainty

Risk Assessment

Module Summary

- The purpose of the Risk Assessment is to:
  - determine whether remedial action is necessary
  - help provide justification for performing remedial action
  - assist in determining what exposure pathways need to be addressed by remedial actions
  - address both human and ecological risks
- Components of human health risk assessment in superfund includes identifying contaminants of concern, assessing exposure and toxicity, and conducting risk characterization
- Radiological and chemical risk assessments are conducted as separate assessments. However, the results of these assessments are not combined, but are considered jointly for a more thorough assessment

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